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Section 5: 510(k) Summary

This section includes a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Terumo Cardiovascular Systems Corporation
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E-mail	Rebecca.andersen@terumomedical.com
Establishment Registration Number	1828100
Name of contact person	Rebecca Andersen, PhD
Date prepared	October 28, 2011
Device Information	
Trade or proprietary name	TLink™ Data Management System (DMS)
Common or usual name	Clinical information management system
Classification name	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Classification panel	74 Cardiovascular
Regulation	870.2450 Medical Cathode-ray tube display
Product Code(s)	DXJ
Legally marketed device(s) to which equivalence is claimed	K012349, MetaVision Clinical Information System
Reason for 510(k)	Traditional 510(k) for new device

Section 5: 510(k) Summary

Device Information	
Device description	The TLink™ DMS consists of the TLink™ software and hardware accessories including computers meeting minimum requirements, data entry devices (barcode laser scanner, touch screen stylus, keyboard), mounting trays and brackets, and serial converters. The system can interface with a variety of external medical devices including, but not limited to, heart-lung machines, blood parameter monitoring systems, centrifugal systems, blood gas devices, patient monitors and anesthesia monitors. Case data can be entered manually by the user or collected automatically from independent medical devices. Screen layouts are customizable to meet hospital and user requirements for patient/case records. Physiological data can be graphed at user defined time intervals for event recording. Certain calculations routinely performed by the clinician during surgery can be performed by the TLink™ DMS, e.g., Body Surface Area (based on patient height and weight data) and Fluid Balance (based on fluid input and output data). Case templates and administrative information are developed on a central computer and transferred to the satellite computer(s) connected to the external medical device(s) in the procedure rooms. Case records are then transferred back to the central computer or hospital information system for central storage and post-case analysis/reporting. All transfers between satellite and central computers are via network and/or removable media. A variety of post-procedure reports are available including case report, clinical activity, case checklist, quality assurance, audit summary report, and audit detail report.
Indication for use	The TLink™ DMS is an electronic clinical record keeping and reporting system indicated for use in collecting, displaying, storing and managing data from external medical devices. The system facilitates the creation of electronic patient records and enables post-procedural case reviews. Data and records can be viewed on local workstations or transferred to a central computer or hospital network for storage and post-case analysis/reporting.

Substantial Equivalence - Summary of the technological characteristics of the TLink™ DMS compared to the predicate device - MetaVision

Characteristic	TLink™ DMS	MetaVision – K012349
Indication for Use	The TLink™ DMS is an electronic clinical record keeping and reporting system indicated for use in collecting, displaying, storing and managing data from external medical devices. The system facilitates the creation of electronic patient records and enables post-procedural case reviews. Data and records can be viewed on local workstations or transferred to a central computer or hospital network for storage and post-case analysis/reporting.	For use in data collection, display, management, and storage in the intensive care unit. The system is used in conjunction with independent patient bedside devices and systems, connected via a network. The way the system is used for generating patient records, computation of drug and fluid dosage and research tasks is determined by the health care providers, in terms of their environment and requirements. The MetaVision application is resident on a workstation that provides for data input and patient data display – to health care professionals. Typically, a MetaVision system comprises several workstations connected via a network system to one or more servers. Data is stored and managed by servers. The MetaVision system network can communicate with a number of remotely located patient care units.
System Components	• System software • Touch screen computer (local to monitoring devices) • Barcode laser scanner and holder • Touch screen stylus	• System software • Local workstations connected via hospital network • Bar code scanner for scanning drug vial bar codes

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Characteristic	TLink™ DMS	MetaVision – K012349
	• Hardware for mounting touch screen computer (trays, brackets)	
Functionality	• Capture device data during procedure and display data in electronic record format customized by the user. Case data can be displayed graphically over time. Clinical events can be marked for subsequent analysis	• Import data from hospital information systems for pre-op evaluations and patient preparation, such as patient medications, lab reports and imaging studies • Capture device data during procedure and display data in electronic record format customized by the user. Case data can be displayed graphically over time. Clinical events can be marked for subsequent analysis
	• Generate reports including diagnoses, clinical data, procedures and outcomes. Reports used for post-procedure analysis and quality assurance	• Generate reports including diagnoses, clinical data, procedures and outcomes. Reports used for post-procedure analysis, quality assurance and billing purposes

Summary of Performance Tests Conducted for Determination of Substantial Equivalence

Characteristic	Report	Results Summary
System & Software Design Verification Testing	Provides documented evidence that the design outputs for TLink™ DMS V. 2.0 continue to meet the existing design inputs of prior software release versions and meet the new design inputs as well. This protocol covers all of the software-related system requirements and includes the additional hardware components.	**Pass** - Test results demonstrate that the design outputs meet the design input requirements (pre-defined acceptance criteria).
System & Software Design Validation Testing	Validates that TLink™ DMS V. 2.0 meets the user needs and intended use under simulated use conditions by addressing the following three areas: • Packaging, Labeling and Miscellaneous • Installation and Set-up • Simulated Use	**Pass** - Test results demonstrate that intended use and user needs are fulfilled.

Conclusion
The TLink™ DMS is substantially equivalent to the MetaVision Clinical Data Management System because it has the same intended use and substantially equivalent performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 7 2012

Terumo Cardiovascular Systems
c/o Dr. Rebecca Andersen
6200 Jackson Rd
Ann Arbor, MI 48103

Re: K113214
Trade/Device Name: TLink Data Management System
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-ray tube display
Regulatory Class: Class II
Product Code: DXJ
Dated: January 17, 2012
Received: January 19, 2012

Dear Dr. Andersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number: K113214

Device Name: TLink™ Data Management System (DMS)

Indications for Use:

The TLink™ DMS is an electronic clinical record keeping and reporting system indicated for use in collecting, displaying, storing and managing data from external medical devices. The system facilitates the creation of electronic patient records and enables post-procedural case reviews. Data and records can be viewed on local workstations or transferred to a central computer or hospital network for storage and post-case analysis/reporting.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113214